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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,164

12/16/2005

Weisheng Tian

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PERKINS COIE LLP

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EXAMINER

BASQUILL, SEAN M

ART UNIT

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1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,164	TIAN ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 Dec 2005; 2 Aug 2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed International application PCT/CN04/00636 under 35 U.S.C. 365(c) is acknowledged.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the claim consists of multiple sentences containing multiple capital letters and periods. *See* MPEP 608.01(m) (indicating each claim begins with a capital letter and ends with a period; periods may not be used elsewhere in the claims except for abbreviations). Appropriate correction is required.

The examiner suggests editing the content of Claim 1 to reflect only the affirmative reaction manipulations, deleting the description of the handling of the "other product" 4-methyl-5-hydroxy pentate or 4-methyl- δ -pentyl lactone) and including, in proper *Markush* form, "wherein" clauses appropriately setting forth the metal catalysts, acids, organic solvents, and

Art Unit: 1612

bases. For example, a proper limitation claiming the group of metal catalysts therein recited may read "wherein the metal catalyst is selected from the group consisting of tungstic oxide, tungstate, vanadic acid, vanadate, vanadyl acetylacetate, molybdic anhydride, molybdate, and phosphomolybdate."

4. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both independent Claim 1 and dependent Claim 3 recite the identical molar ratio ranges, 1:1.0-4.0:0.001-1:0-1 of which 1:1.5-2.5:0.005-0.02:0 is preferred.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See, e.g., In re*

Art Unit: 1612

Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Mere indistinct terms (such as “analogs” of 16-dehydropregnenolone or steroidal sapogenin, or heteroacids and heteropolyates used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Univ. of Calif. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to

Art Unit: 1612

the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful steroid sapogenin or 16-dehydropregnenolone analogs generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. In fact, the specification fails to disclose any analogs of the steroid sapogenins or 16-dehydropregnenolone as taught in instant Claims 1, 2, and 4, thereby failing to either disclose a sufficient number of species or indicate which structural moieties or modifications would constitute “analog” within the scope of the instant Claims.

Furthermore, the specification fails to indicate what is meant by the metal catalysts “heteropolyacid and heteropolyate” as put forth in Claim 1.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “analog” is indefinite because it is unclear how far one can deviate from the parent compound without the “analog” being so far removed therefrom as to be a completely different compound. See the related rejection in the “Written Description” section *supra*.

Additionally, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 3 recite the broad recitation "wherein the molar ratio [of reaction ingredients] is 1:1.0-4.0:0.001-1:0-1," and the claim also recites "of which [the molar ratio of reaction ingredients] 1:1.5-2.5:0.005-0.02:0 is preferred," which is the narrower statement of the range/limitation.

The language and formatting of Claim 1 makes unclear the identity of the starting material of the reaction steps outlined in the remainder of the claim, rendering the claim indefinite. Specifically, the phrase "the pure or the crude pseudo steroidal sapogenin, derived from steroidal sapogenin," taken with the structure disclosed in Claim 1 as "[t]he mentioned steroidal sapogenin" renders uncertain the precise starting material to be used. In addition, neither the Claims nor the specification clearly define what is meant by "pseudo steroidal sapogenin."

Art Unit: 1612

7. Claim 1 recites the limitation "the base." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966),

that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinese Patent Application Publication 1341603 (hereinafter "Tian") (of record), in view of Robert Thornton Morrison & Robert Neilson Boyd, ORGANIC CHEMISTRY 486-87 (Allyn and Bacon, Inc., 1965) (1959) (hereinafter "Morrison").

The examiner would like to note that the irregular language and format of the instant claims has made claim interpretation and therefore examination of the instant claims rather difficult. The examiner contends that the instant Claims, for example Claim 1, recite a method of producing 16-dehydropregnenolone by subjecting a steroidal sapogenin to reaction conditions

Art Unit: 1612

including hydrogen peroxide, and optionally a metal compound and acid as catalysts where the molar ratios of the sapogenin, hydrogen peroxide, metal catalyst, and acid are 1:1.0-4.0:0.001-1:0-1, the steroidal sapogenin is of the recited glucoside structure, and the metal catalyst, acid, organic solvents, and base are selected from the Markush-type groups presented. Additionally, it appears as though Claim 1 also recites a further step of washing the product of the peroxide/metal/acid reaction with a basic solution to yield the final product.

Tian describes the manufacture of pregnene keto alcohols by subjecting the crude product to a reaction environment of hydrogen peroxide, a metal catalyst and acid for a period of 0.1-24 hours using the reaction conditions as recited in the instant claims. The metal catalysts used include molybdate, phosphomolybdate, and molybdic anhydride; the acid may be acetic, formic, propionic, sulfuric, or phosphoric acids, and the solvents include t-butanol, acetone, butanone, and ethyl acetate. Tian indicates that the keto-alcohol obtained is valuable as a precursor for the synthesis of pharmaceutical steroids.

Tian does not describe reaction conditions including a final basic wash of the reaction compounds with compounds such as sodium hydroxide, nor does Tian describes the formation of sapogenin, instead describing a reaction which results in an acetate, distinguishable from the instant sapogenins by the presence of an acetate moiety at the 3-position.

Morrison describes the hydrolysis of acetates using strong bases such as sodium hydroxide resulting in the formation of an acetate salt and alcohol. (Pg. 486-87).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have added the basic acetate hydrolysis step of Morrison to the reaction of Tian to provide a method of sapogenin production Claimed in the instant application.

Art Unit: 1612

One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the recognized utility of the free alcohol form of 16-dehydropregnenolone in the synthesis of pharmaceutical steroids and the simplicity of forming an alcohol from an acetate.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/561,164

Page 10

Art Unit: 1612

Sean Basquill

Art Unit 1612

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642